General

Guideline Title

Clinical policy: critical issues in the initial evaluation and management of patients presenting to the emergency department in early pregnancy.

Bibliographic Source(s)

Hahn SA, Promes SB, Brown MD, American College of Emergency Physicians. Clinical policy: critical issues in the initial evaluation and management of patients presenting to the emergency department in early pregnancy. Ann Emerg Med. 2017 Feb;69(2):241-50.e20. [40 references] PubMed

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Hahn SA, Lavonas EJ, Mace SE, Napoli AM, Fesmire FM, American College of Emergency Physicians. Clinical policy: critical issues in the initial evaluation and management of patients presenting to the emergency department in early pregnancy. Ann Emerg Med. 2012 Sep;60(3):381-90.e28. [55 references]

This guideline meets NGC's 2013 (revised) inclusion criteria.

Recommendations

Major Recommendations

Definitions for the strength of evidence (Class I-III) and strength of recommendations (A-C) are provided at the end of the "Major Recommendations" field.

1. Should the emergency physician obtain a pelvic ultrasound in a clinically stable pregnant patient who presents to the emergency department (ED) with abdominal pain and/or vaginal bleeding and a beta-human chorionic gonadotropin (β-hCG) level below a discriminatory threshold?
   Patient Management Recommendations

   Level A recommendations. None specified.

   Level B recommendations. Perform or obtain a pelvic ultrasound for symptomatic pregnant patients with any β-hCG level.

   Level C recommendations. None specified.

2. In patients who have an indeterminate transvaginal ultrasound result, what is the diagnostic utility of β-hCG for predicting possible ectopic pregnancy?
   Patient Management Recommendations

Level A recommendations. None specified.

Level B recommendations. Do not use the β-hCG value to exclude the diagnosis of ectopic pregnancy in patients who have an indeterminate ultrasound result.

Level C recommendations. Obtain specialty consultation or arrange close outpatient follow-up for all patients with an indeterminate pelvic ultrasound result.

Definitions

Strength of Evidence

*Literature Classification Schema**

Design/Class	Therapy†	Diagnosis‡	Prognosis§
1	Randomized controlled trial or meta-analysis of randomized trials	Prospective cohort using a criterion standard or meta-analysis of prospective studies	Population prospective cohort or meta-analysis of prospective studies
2	Nonrandomized trial	Retrospective observational	Retrospective cohort Case control
3	Case series	Case series	Case series

*Some designs (e.g., surveys) will not fit this schema and should be assessed individually.

†Objective is to measure therapeutic efficacy comparing interventions.

‡Objective is to determine the sensitivity and specificity of diagnostic tests.

§Objective is to predict outcome, including mortality and morbidity.

*Approach to Downgrading Strength of Evidence**

Downgrading	Design/Class		
	1	2	3
None	I	II	III
1 level	II	III	X
2 levels	III	X	X
Fatally flawed	X	X	X

*See the "Description of Methods Used to Analyze the Evidence" field for more information.

Strength of Recommendations

Strength of recommendations regarding each critical question were made by subcommittee members using results from strength of evidence grading, expert opinion, and consensus among subcommittee members according to the following guidelines:

Level A recommendations. Generally accepted principles for patient care that reï¬ect a high degree of clinical certainty (e.g., based on evidence from 1 or more Class of Evidence I or multiple Class of Evidence II studies).

Level B recommendations. Recommendations for patient care that may identify a particular strategy or range of strategies that reï¬ect moderate clinical certainty (e.g., based on evidence from 1 or more Class of Evidence II studies or strong consensus of Class of Evidence III studies).

Level C recommendations. Recommendations for patient care that are based on evidence from Class of Evidence III studies or, in the absence of any adequate published literature, based on expert consensus. In instances where consensus recommendations are made, "consensus" is placed in parentheses at the end of the recommendation.

There are certain circumstances in which the recommendations stemming from a body of evidence should not be rated as highly as the individual studies on which they are based. Factors such as heterogeneity of results, uncertainty about effect magnitude and consequences, and publication

bias, among others, might lead to such a downgrading of recommendations.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

- Abdominal pain and/or vaginal bleeding in the first trimester of pregnancy (also referred to as "early pregnancy")
- Ectopic pregnancy

Guideline Category

Diagnosis

Evaluation

Management

Clinical Specialty

Emergency Medicine

Internal Medicine

Obstetrics and Gynecology

Intended Users

Physicians

Guideline Objective(s)

To derive evidence-based recommendations to help clinicians answer the following critical questions:

- Should the emergency physician obtain a pelvic ultrasound in a clinically stable pregnant patient who presents to the emergency department with abdominal pain and/or vaginal bleeding and a beta-human chorionic gonadotropin (β-hCG) level below a discriminatory threshold?
- In patients who have an indeterminate transvaginal ultrasound result, what is the diagnostic utility of β-hCG for predicting possible ectopic pregnancy?

Target Population

Stable patients (with normal blood pressure and pulse rate) presenting to the emergency department in the first trimester of pregnancy who have abdominal pain or vaginal bleeding, without a previously confirmed intrauterine pregnancy

Note: This guideline is not intended to address the care of patients who are clinically unstable, have had abdominal trauma, or are at higher risk for heterotopic pregnancy such as those who are undergoing fertility treatments.

Interventions and Practices Considered

1. Assessment of serum beta-human chorionic gonadotropin (β-hCG) levels
2. Pelvic ultrasound
3. Specialty consultation or close outpatient follow-up for patients with an indeterminate pelvic ultrasound

Major Outcomes Considered

Sensitivity and specificity of diagnostic tests

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

This clinical policy was created after careful review and critical analysis of the medical literature and was based on a systematic review of the literature. Searches of MEDLINE, MEDLINE InProcess, Scopus, Web of Science, and the Cochrane Database were performed. All searches were limited to English-language sources and human studies. Specific key words/phrases, years used in the searches, dates of searches, and study selection are identified under each critical question for questions 1 and 2 and in the "Introduction" section of the original guideline document for the topics of methotrexate therapy and anti-D immunoglobulin administration. In addition, relevant articles from the bibliographies of included studies and more recent articles identified by committee members and reviewers were included.

Number of Source Documents

Study Selection

Critical Question 1

Two hundred thirty-five articles were identified in the search. Five articles were selected from the search results for further review, with zero new articles included for this critical question.

Critical Question 2

Eighty-one articles were identified in the search. Six articles were selected from the search results for further review, with zero new articles included for this critical question.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Strength of Evidence

Literature Classification Schema*

Design/Class	Therapy†	Diagnosis‡	Prognosis§
1	Randomized controlled trial or meta-analysis of randomized trials	Prospective cohort using a criterion standard or meta-analysis of prospective studies	Population prospective cohort or meta-analysis of prospective studies
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*Some designs (e.g., surveys) will not fit this schema and should be assessed individually.

†Objective is to measure therapeutic efficacy comparing interventions.

‡Objective is to determine the sensitivity and specificity of diagnostic tests.

§Objective is to predict outcome, including mortality and morbidity.

Approach to Downgrading Strength of Evidence*

Downgrading	Design/Class		
	1	2	3
None	I	II	III
1 level	II	III	X
2 levels	III	X	X
Fatally flawed	X	X	X

*See the "Description of Methods Used to Analyze the Evidence" field for more information.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Assessment of Classes of Evidence

All articles used in the formulation of this clinical policy were graded by at least 2 methodologists and assigned a Class of Evidence. Each article was assigned a design class with design 1 representing the strongest study design and subsequent design classes (i.e., design 2 and design 3) representing respectively weaker study designs for therapeutic, diagnostic, or prognostic clinical reports, or meta-analyses (see the "Rating Scheme for the Strength of the Evidence" field). Articles were then graded on dimensions related to the study's methodological features, such as randomization processes, blinding, allocation concealment, methods of data collection, outcome measures and their assessment, selection and misclassification biases, sample size, and generalizability. Using a predetermined process related to the study's design, methodological quality, and applicability to the critical question, articles received a final Class of Evidence grade (i.e., Class I, Class II, Class III, or Class X) (see the "Rating Scheme for the Strength of the Evidence" field). Articles identified with fatal flaws or that were ultimately not applicable to the critical question received a Class of Evidence grade "X" and were not used in formulating recommendations for this policy. Grading was done with respect to the specific critical questions; thus, the level of evidence for any one study may vary according to the question for which it is being considered. As such, it was possible for a single article to receive different Classes of Evidence as different critical questions were answered from the same study. Question-specific level of evidence grading may be found in the Evidentiary Table at the end of the original guideline document.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

This policy is a product of the American College of Emergency Physicians (ACEP) clinical policy development process, including expert review, and is based on the existing literature; where literature was not available, consensus of emergency physicians was used.

When possible, clinically oriented statistics (e.g., likelihood ratios [LRs], number needed to treat) are presented to help the reader better understand how the results may be applied to the individual patient. For a definition of these statistical concepts, see Appendix C in the original guideline document.

Rating Scheme for the Strength of the Recommendations

Translation of Classes of Evidence to Recommendations

Strength of recommendations regarding each critical question were made by subcommittee members using results from strength of evidence grading, expert opinion, and consensus among subcommittee members according to the following guidelines:

Level A recommendations. Generally accepted principles for patient care that reflect a high degree of clinical certainty (i.e., based on evidence from 1 or more Class of Evidence I or multiple Class of Evidence II studies).

Level B recommendations. Recommendations for patient care that may identify a particular strategy or range of strategies that reflect moderate clinical certainty (e.g., based on evidence from 1 or more Class of Evidence II studies or strong consensus of Class of Evidence III studies).

Level C recommendations. Recommendations for patient care that are based on evidence from Class of Evidence III studies or, in the absence of any adequate published literature, based on expert consensus. In instances where consensus recommendations are made, "consensus" is placed in parentheses at the end of the recommendation.

There are certain circumstances in which the recommendations stemming from a body of evidence should not be rated as highly as the individual studies on which they are based. Factors such as heterogeneity of results, uncertainty about effect magnitude and consequences, and publication bias, among others, might lead to such a downgrading of recommendations.

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

Expert review comments were received from individual emergency physicians, individual members of the American Congress of Obstetricians and Gynecologists (ACOG) and the American Institute of Ultrasound in Medicine (AIUM), and members of the American College of Emergency Physicians' (ACEP's) Ultrasound Section and Medical Legal Committee. Comments were received during a 60-day open comment period, with notices of the comment period sent in an e-mail to ACEP members, published in *EM Today*, and posted on the ACEP Web site. The responses were used to further refine and enhance this policy; however, the responses do not imply endorsement of this clinical policy.

This clinical policy was approved by the ACEP Board of Directors on October 13, 2016.

This guideline was endorsed by the Emergency Nurses Association on November 29, 2016.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Recommendations were based on 10 Class II and 10 Class III studies.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

- Improved patient safety by decreasing the risk of missing an ectopic pregnancy among patients with a low beta-human chorionic gonadotropin (β-hCG) value. In addition, the potential for earlier diagnosis of a viable intrauterine pregnancy in many patients will likely reduce the need for further follow-up testing for ectopic pregnancy.
- Reduced risk of missing an ectopic pregnancy in patients with an indeterminate ultrasound result

Potential Harms

- Increased use of ultrasound with associated costs and increased emergency department (ED) length of stay for patients, as well as a potential increase in unnecessary specialty consultations for false-positive or equivocal ultrasound results
- Additional resource use, including potential admissions and/or an increase in invasive management of patients without an ectopic pregnancy who have an indeterminate ultrasound result

Qualifying Statements

Qualifying Statements

- Policy statements and clinical policies are the official policies of the American College of Emergency Physicians (ACEP) and, as such, are not subject to the same peer review process as articles appearing in the journal. Policy statements and clinical policies of ACEP do not necessarily reflect the policies and beliefs of *Annals of Emergency Medicine* and its editors.
- This policy is not intended to be a complete manual on the evaluation and management of patients presenting to the emergency department (ED) in early pregnancy but rather a focused examination of critical issues that have particular relevance to the current practice of emergency medicine.
- It is the goal of the Clinical Policies Committee to provide an evidence-based recommendation when the medical literature provides enough quality information to answer a critical question. When the medical literature does not contain adequate empirical data to answer a critical question, the members of the Clinical Policies Committee believe that it is equally important to alert emergency physicians to this fact.
- This clinical policy is not intended to represent a legal standard of care for emergency physicians. Recommendations offered in this policy are not intended to represent the only diagnostic or management options available to the emergency physician. ACEP recognizes the importance of the individual physician's judgment and patient preferences. This guideline defines for the physician those strategies for which medical literature exists to provide support for answers to the critical questions addressed in this policy.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Mobile Device Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

IOM Domain

Effectiveness

Identifying Information and Availability

Bibliographic Source(s)

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Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2017 Feb

Guideline Developer(s)

American College of Emergency Physicians - Medical Specialty Society

Source(s) of Funding

The American College of Emergency Physicians was the funding source for this clinical policy.

Guideline Committee

American College of Emergency Physicians (ACEP) Clinical Policies Subcommittee (Writing Committee) on Early Pregnancy

ACEP Clinical Policies Committee (Oversight Committee)

Composition of Group That Authored the Guideline

Members of the Subcommittee (Writing Committee) on Early Pregnancy: Sigrid A. Hahn, MD, MPH (*Subcommittee Chair*); Susan B. Promes, MD, MBA; Michael D. Brown, MD, MSc (*Committee Chair*)

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Financial Disclosures/Conflicts of Interest

Relevant industry relationships: There were no relevant industry relationships disclosed by the subcommittee members.

Relevant industry relationships are those relationships with companies associated with products or services that significantly impact the specific aspect of disease addressed in the critical question.

Guideline Endorser(s)

Emergency Nurses Association - Professional Association

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Hahn SA, Lavonas EJ, Mace SE, Napoli AM, Fesmire FM, American College of Emergency Physicians. Clinical policy: critical issues in the initial evaluation and management of patients presenting to the emergency department in early pregnancy. Ann Emerg Med. 2012 Sep;60(3):381-90.e28. [55 references]

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Available from the American College of Emergency Physicians (ACEP) Web site .

A summary of this guideline optimized for mobile viewing is available under the CQ tab at the ACEP Web site .

Availability of Companion Documents

The following are available:

- American College of Emergency Physicians clinical policy development. Irving (TX): American College of Emergency Physicians (ACEP); 3 p. Available from the American College of Emergency Physicians (ACEP) Web site .
- ACEP clinical policy development process. Flow chart. Irving (TX): American College of Emergency Physicians (ACEP); 1 p. Available from the ACEP Web site .

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI on June 5, 2003. The information was verified by the guideline developer on July 18, 2003. This summary was updated by ECRI Institute on September 28, 2012. The updated information was verified by the guideline developer on October 23, 2012. This summary was updated by ECRI Institute on March 30, 2017. The updated information was verified by the guideline developer on April 12, 2017.

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